

### REMARKS

Claims 40, 42, 43, 103, and 111-151 are pending. Claims 43, 127, 128, 133, and 135 are provisionally rejected for obviousness-type double patenting. Claims 40, 42, 43, 103, 111-118, 120, 121, 127-131, 133-135, and 138-146 are rejected under 35 U.S.C. § 102(e) for anticipation by Constantz et al. (U.S. Patent No. 5,962,028; hereinafter “Constantz”). Claims 40, 42, 43, 103, 113-120, 126-128, 130-134, 138, 140-145, and 148 are rejected under 35 U.S.C. § 102(e) for anticipation by Brown et al. (U.S. Patent No. 6,201,039; hereinafter “Brown”). Claims 40, 42, 43, 103, 111-118, 120-123, 125, 127-131, 133-147, and 149-151 are rejected under 35 U.S.C. § 103(a) for obviousness over Constantz. Finally, claims 40, 42, 43, 103, and 111-151 are rejected under 35 U.S.C. § 103(a) for obviousness over Brown or Constantz in view of Fukase et al. (J. Dent. Res. 69:1852-1856, 1990; hereinafter “Fukase”) and Tung (U.S. Patent No. 5,037,639; hereinafter “Tung”). By this reply, Applicants cancel claim 144, amend claims 42, 133, and 138, add new claims 152 and 153, and address each of the Examiner’s rejections below.

### Support for the Amendment

Support for the amendment to claim 42 is found in the specification on, e.g., page 12, lines 17-19, and page 38, lines 6-26. Claims 133 has been amended to correct typographical errors. Support for the amendment to claim 138 is found in prior claim 144. Support for new claim 152 is found in the specification on, e.g., page 37, lines 23-27. Support for new claim 153 is found in the specification on, e.g., page 38, lines 6-17. No new matter is added by the amendment.

### Provisional Obviousness-type Double Patenting Rejections

The Examiner rejects claims 43, 127, 128, 133, and 135 for provisional obviousness-type double patenting over claims 18 and 21 of copending U.S. Serial No. 09/993,739. The Examiner states that “[a]lthough the conflicting claims are not identical, they are not patentably distinct from each other because the ‘739 application and [the] current application claim variants, obvious, of the same subject matter” (Office Action, p. 2).

The M.P.E.P. § 804(I)(B) states that:

the “provisional” double patenting rejection should continue to be made by the examiner in each application as long as there are conflicting claims in more than one application unless that “provisional” double patenting rejection is the only rejection remaining in one of the applications. If the “provisional” double patenting rejection in one application is the only rejection remaining in that application, the examiner should then withdraw that rejection and permit the application to issue as a patent, thereby converting the “provisional” double patenting rejection in the other application(s) into a double patenting rejection at the time the one application issues as a patent.

Therefore, Applicants will address the provisional obviousness-type double patenting rejection in the present case once otherwise allowable subject matter has been determined in this application or the copending ‘739 application.

### Rejections under 35 U.S.C. § 102

#### *Constantz*

Claims 40, 42, 43, 103, 111-118, 120, 121, 127-131, 133-135, and 138-146 are rejected under 35 U.S.C. § 102(e) for anticipation by Constantz. The Examiner states that Constantz anticipates claims 40, 42, 43, 103, 111-118, 120, 121, 127-131, 133-135, and 138-146 because the terminology used in Applicants’ claims (i.e., “pressing said powders to form a compressed

object” or “a compressed powder object”) is without quantification (i.e., the claims recite no particular time, pressure, shape, or dimension limitation; Office Action, pp. 2-3). Further, the Examiner states that the “compressed materials” of Constantz that are “formed by rolling would be seen as resulting in a compressed product or object” (Office Action, p. 2). Applicants respectfully disagree.

Constantz, which was discussed in the previous Reply to Office Action filed on July 17, 2003, discloses carbonated hydroxyapatite compositions that are formed by mixing the dry ingredients (i.e., a phosphoric acid source, an alkali earth metal source, and a calcium carbonate) using mills or rollers “until a uniform dispersal of ingredients is obtained” (see, e.g., col. 4, lines 40-42, col. 5, lines 17-13, and col. 5, line 66, through col. 6, line 7). A lubricant is then added to the mixed dry ingredients in an amount to form a flowable “paste” or moldable “clay-like putty,” which subsequently hardens (col. 6, lines 10-36). Constantz also discloses that shaping of the composition may occur prior to, during, or after hardening of the paste or putty (i.e., after hydrating the dry powder component; see col. 7, lines 60-62).

The pending claims, as presently amended, include five independent claims: claims 40, 42, 43, 103, and 138. Independent claims 42 and 43 are directed to bioceramic compositions, independent claims 40 and 138 are directed to methods of preparing bioceramic compositions, and claim 103 is directed to a method of treating a bone defect using a bioceramic composition. The M.P.E.P. § 2131 states that “‘A claim is anticipated only if each and every element as set forth in the claims is found, either expressly or inherently described, in a single prior art reference.’ *Verdegaal Bros. v. Union Oil Co. of California* 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).” As is discussed below, independent claims 40, 42, 43, 103, and 138 recite one or more

elements that are not taught or suggested by Constantz. Applicants address the present rejection over Constantz with respect to each of the independent claims in the following order: composition claims, method of preparation claims, and method of treating claims.

#### **Independent Claim 42 is not Anticipated by Constantz**

Independent claim 42, as presently amended, recites a composite material that includes a strongly bioresorbable, poorly crystalline apatitic (PCA) calcium phosphate having a Ca/P ratio of less than 1.5, which is in contact with a supplemental material that is present in an amount effective to impart a characteristic selected from the group consisting of strength, resorption time, adherence, frictional characteristics, release kinetics, tensile strength, hardness, fracture toughness, elasticity, and imaging capability. Claim 42 has been amended to recite that the supplemental material is selected from a bioresorbable material selected from the group consisting of silk, demineralized bone matrix, hyaluronic acid and derivatives thereof, polyanhydrides, polyorthoesters, polyglycolic acid, polylactic acid, and copolymers thereof, polyesters of  $\alpha$ -hydroxycarboxylic acids, poly(L-lactide) (PLLA), poly(D,L-lactide) (PDLLA), polyglycolide (PGA), poly(lactide-co-glycolide) (PLGA), poly(D,L-lactide-co-trimethylene carbonate), and polyhydroxybutyrate (PHB), polyanhydrides, poly(anhydride-co-imide) and copolymers thereof, and bioactive glass compositions; a non-bioresorbable material selected from the group consisting of dextrans, polyethylene, polymethylmethacrylate (PMMA), carbon fibers, polyvinyl alcohol (PVA), poly(ethylene terephthalate)polyamide, bioglasses, calcium sulfate, and calcium phosphates; a lubricant selected from the group consisting of silicone oil, polymer waxes, lipids, and fatty acids, a non-bioresorbable material, a lubricant, and a radiographic

material. As is discussed above, Constantz discloses the preparation of a dahllite-like composition referred to as carbonated hydroxyapatite. Constantz states:

Various additional components may be included during the formation of the carbonated hydroxyapatite, dahllite. Of particular interest are pharmacologically active agents, proteins, polysaccharides, or other biocompatible polymers, or the like. Of particular interest are proteins involved in skeletal structure such as different forms of collagen, especially Type I, fibrin, fibrinogen, keratin, tubulin, elastin, and the like, or structural polysaccharides, such as chitin. Pharmacologically active agents might include drugs that enhance bone growth, serve as a variety of cell growth factors, or act as anti-inflammatory or anti-microbial agents. Examples of such proteins might include but not be limited to: bone morphogenetic protein, cartilage induction factor, platelet derived growth factor, and skeletal growth factor. (See col. 6, line 61, through col. 7, line 5.)

As is apparent from the above passage, Constantz fails to teach or suggest combining any of the supplemental materials recited in present claim 42 with the carbonated hydroxyapatite.

Therefore, Constantz fails to teach or suggest all of the elements of present claim 42, and claims dependent therefrom, as is required (see M.P.E.P. § 2131, *supra*). Thus, claim 42 is distinguishable over Constantz and the rejection of claim 42 under 35 U.S.C. § 102(e) over Constantz should be withdrawn. Furthermore, the rejection under 35 U.S.C. § 102(e) over Constantz should not be applied to new claims 152 and 153, which depend from claim 42.

#### **Independent Claim 43 is not Anticipated by Constantz**

Independent claim 43 is directed to a bioceramic composition comprising a *compressed* powder object of a predetermined shape. As was discussed in the previous Reply to Office Action, filed on July 17, 2003, a “compressed powder object” is one in which the powder components have been pressed or squeezed together by the application of pressure. Applicants specification clearly explains that such pressure may be applied by, for example, a hand-held

press or a hydraulic press (see, e.g., p. 61, lines 19-27, and p. 88, line 20, through page 89, line 29).

The Examiner argues that Constantz discloses “compressed materials” formed by rolling, and that this meets the limitations of present claim 43, and claims dependent therefrom, because “rolling would be seen as resulting in a compressed product or object” (Office Action, p. 2).

Constantz clearly and unambiguously discloses that mixing of the dry components is used to combine the ingredients so that a uniform dispersal is obtained. Constantz states:

Mixing will be used to combine the ingredients and can be used to regulate the extent of the inter-ingredient reactions. Any or all of the dry ingredients may be added prior to the initiation of mixing or prior to the completion of mechanical mixing. Methods of mixing can include ball milling, Brabender mixing, rolling between one or more rollers and a flexible container, or the like. Preferably, mixing will be thorough and will occur for a relatively short time or until a uniform dispersal of ingredients is obtained. (See col. 5, line 67, through col. 6, line 9; emphasis added.)

Based on the following passage it is clear that Constantz’s “rolling” of the dry ingredients does not result in a compressed object. Rather, “rolling” by the Constantz method clearly results in a thoroughly mixed and uniformly dispersed (i.e., non-compressed) powder. Therefore, Constantz fails to teach or suggest the preparation of a compressed powder object, as is recited in present claim 43. Thus, the rejection of claim 43, and claims dependent therefrom, under 35 U.S.C. § 102(e) over Constantz should be withdrawn.

#### **Independent Claim 40 is not Anticipated by Constantz**

Independent claim 40 is directed to a method for preparing a bioceramic composition. Claim 40 recites mixing powders of a calcium phosphate and a promoter, pressing the powders to form a compressed object of predetermined shape, and hydrating the compressed powder object.

The Examiner argues that claim 40 is anticipated by Constantz because “[c]laim 3 [of Constantz] mixes, presses and hydrates the same materials as applicant and achiever [sic] a high compressive strength composition” (Office Action, p. 3). This is incorrect.

Claim 3 of Constantz is directed to a bioresorbable paste that is prepared by mechanically mixing at least one calcium source, a partially neutralized phosphoric acid free of uncombined water, a carbonate source, and an aqueous lubricant. Claim 3 simply fails to describe a step in which the dry ingredients are compressed prior to hydration. Claim 3 merely describes mixing both the dry and the liquid ingredients to form the paste. Therefore, claim 3 cannot be relied upon to support the argument that Constantz discloses the compressed powder of present claim 43, and claims dependent therefrom. Furthermore, as is discussed above, the remaining disclosure of Constantz also fails to teach or suggest the formation of a compressed powder object. Therefore, Constantz fails to disclose each and every method step of claim 40. Accordingly, the rejection of claim 40, and claims dependent therefrom, under 35 U.S.C. § 102(e) over Constantz should be withdrawn.

#### **Independent Claim 138 is not Anticipated by Constantz**

Independent claim 138 is also directed to a method for preparing a bioceramic composition. As presently amended, claim 138 recites mixing powders of a calcium phosphate and a promoter selected from calcium metaphosphate, dicalcium phosphate dihydrate, heptacalcium decaphosphate, calcium pyrophosphate dihydrate, poorly crystalline apatitic (PCA) calcium phosphate, calcium pyrophosphate, monetite, octacalcium phosphate, CaO, calcium acetate,  $H_2PO_4$ , and amorphous calcium phosphate in a hydrating medium to form a paste,

introducing the paste into a mold of a predetermined shape, and allowing the paste to harden into a PCA calcium phosphate article. The Examiner argues that Constantz anticipates claim 138, and claims dependent therefrom, because Constantz discloses shaped articles. The passage cited by the Examiner states:

The compositions can be used to substitute many of the functions of naturally occurring calcified tissues or in the repair of such tissues, in particular teeth and bone. The dahllite or francolite-like products can be readily formed by combining the wet and dry reactants to provide a substantially uniform mixture, shaping the mixture as appropriate, and allowing the mixture to harden. (See col. 4, lines 44-51.)

As is clear from this passage, Constantz discloses the preparation of a formable dahllite or francolite-like product (i.e., a carbonated hydroxyapatite) that can shaped prior to, or following, hardening. Absent from the disclosure of Constantz, though, is a teaching or suggestion to prepare the dahllite or francolite-like product by combining a calcium phosphate and promoter selected from the ones listed in present claim 138. The method recited by present claim 138 is taught solely by Applicants' specification. Because Constantz fails to teach or suggest every element of present claim 138, the requirements for establishing a rejection under 35 U.S.C. § 102 have not been met (see M.P.E.P. § 2131, *supra*). Therefore, Applicants respectfully request that the rejection of claims 138-143 and 145-148 under 35 U.S.C. § 102(e) over Constantz be withdrawn.

#### **Independent Claim 103 is not Anticipated by Constantz**

Independent claim 103 is directed to a method for treating a bone defect by introducing a compressed powder object at the bone site. As is discussed above, Constantz fails to teach or



suggest the preparation of a compressed powder object. For this reason, Applicants respectfully request that the rejection of claim 103 under 35 U.S.C. § 102(e) for anticipation by Constantz be withdrawn.

*Brown*

Claims 40, 42, 43, 103, 113-120, 126-128, 130-134, 138, 140-145, and 148 are rejected under 35 U.S.C. § 102(e) for anticipation by Brown. The Examiner argues that Brown discloses a powder mixture containing calcium phosphate, a promoter, such as the ones recited in present claim 118, and calcium carbonate, and that such a mixture results in the formation of “a formed product” that meets the limitations of present claims 40, 42, 43, 103, and 138. The Examiner also argues that the “particles” described by Brown in Example 12 cannot be distinguished from the compressed powder object recited in claims 40, 43, and 103, and claims dependent therefrom. Applicants respectfully traverse this rejection. Applicants first address the present rejection over Brown with respect to independent claims 40, 43, and 103.

**Independent Claims 40, 43, and 103 are not Anticipated by Brown**

Brown describes polymineralic particles, which are precursors of hydroxyapatite, and a method for their production (see, e.g., the abstract of Brown). Brown states that the polymineralic particles form hydroxyapatite in the absence of additional sources of calcium and phosphate by a method that involves:

reacting at least one calcium source, with at least one acid phosphate source having at least 2 protons attached to one phosphate, in a non-aqueous liquid for a time sufficient to form said polymineralic precursors particles comprising  $\text{Ca}_x(\text{PO}_4)_y$  and unreacted calcium source said polymineralic precursor particles having

an overall Ca/P ratio of 1.5 to 1.67. (See, e.g., col. 5, lines 48-57.)

Brown further discloses that preparation of the polymineralic particles involves:

firing an intimate mixture of equimolar amounts of  $\text{CaCO}_3$  and  $\text{CaHPO}_4$  powders to  $1400^\circ\text{C}$ . for 4 hours. After cooling the  $\text{Ca}_4(\text{PO}_4)_2\text{O}$  is ground to an average particle size of 2-5  $\mu\text{m}$  using standard powder preparation techniques. This material is then reacted with the acidic phosphate source  $\text{Ca}(\text{H}_2\text{PO}_4) \cdot \text{H}_2\text{O}$ , which is commercially available, by placing it and  $\text{Ca}_4(\text{PO}_4)_2\text{O}$  in a 1-liter polyethylene bottle with approximately 400 ml of heptane.

Approximately 250 g of zirconia or alumina, or 100 g polycarbonate pellets are added and the bottle is sealed. The presence of the pellets limits agglomeration. This bottle is then placed in any shaking or rolling device. In the reaction, all of the  $\text{Ca}(\text{H}_2\text{PO}_4) \cdot \text{H}_2\text{O}$  and some of the  $\text{Ca}_4(\text{PO}_4)_2\text{O}$  are consumed in the formation of the polymineralic precursor particles comprising  $\text{Ca}_4(\text{PO}_4)_2\text{O}$  and  $\text{Ca}_x(\text{PO}_4)_y$ . These produced polymineralic particles can then react rapidly in the presence of water to form hydroxyapatite in vivo. (See col. 13, lines 38-55; emphasis added.)

Thus, Brown's dry ingredients are ground to achieve small particle size and then shaken in a manner that specifically prevents agglomeration of the dry component particles. Therefore, Brown's method would preclude the formation of a compressed powder object, as is recited by present claims 40, 43, and 103, and claims dependent therefrom. Because Brown fails to teach or suggest the preparation of a compressed powder object, Brown fails to teach or suggest all of the elements of present claims 40, 43, and 103, and claims dependent therefrom.

In addition, the Examiner argues that the "open language [of the present claims] permits some other materials hydrated forms" (Office Action, p. 3). As argued in the previous Reply to Office Action, Applicants again point out that the Examiner's argument improperly ignores the word "powder" in Applicants' claims. The explicit language of independent claims 40, 43, and 103 specifies that the object is a "compressed powder object." Applicants also point out that "hydrating," as is recited in the method of present claim 40, refers to the hydration of the compressed powder object. Hydrating the powder component prior to the formation of the

compressed powder object would fail to yield the compressed powder object recited in present claims 40, 43, and 103, and would not accomplish the method steps of present claim 40.

Therefore, Brown simply fails to teach or suggest the formation of a compressed powder object or the hydration of a compressed powder object. Accordingly, Applicants respectfully request that the rejection of claims 40, 43, and 103, and claims 113-120, 126-128, and 130-134 dependent therefrom, under 35 U.S.C. § 103(a) for anticipation by Brown should be withdrawn.

**Independent Claim 42 is not Anticipated by Brown**

Brown also fails to teach or suggest all of the elements of present claim 42. As is discussed above, claim 42, as presently amended, is directed to a composite material comprising a PCA calcium phosphate having a Ca/P ratio of less than 1.5 in combination with a supplemental material selected from among those listed in claim 42. Brown states:

In the reaction of the calcium source with the acidic phosphate source, the molar ratio or amount of calcium source to acidic phosphate source employed is not critical so long as the overall Ca/P ratio in the produced polymineralic precursor particles is in the range of 1.5 to 1.67 and can be ascertained by one skilled in the art. (See col. 7, lines 50-55.)

Because Brown fails to teach or suggest that the hydroxyapatite composition could or should have a Ca/P ratio of less than 1.5, Brown fails to teach or suggest all of the elements of present claim 42. Therefore, the rejection of claim 42 under 35 U.S.C. § 103(a) for anticipation by Brown should be withdrawn. Furthermore, the rejection of claim 42 over Brown should not be applied to new claims 152 and 153.

### **Independent Claim 138 is not Anticipated by Brown**

As is discussed above, independent claim 138, as presently amended, is directed to a method for preparing a bioceramic composition by mixing powders of a calcium phosphate and a promoter selected from calcium metaphosphate, dicalcium phosphate dihydrate, heptacalcium decaphosphate, calcium pyrophosphate dihydrate, poorly crystalline apatitic (PCA) calcium phosphate, calcium pyrophosphate, monetite, octacalcium phosphate, CaO, calcium acetate,  $H_2PO_4$ , and amorphous calcium phosphate in a hydrating medium to form a paste, introducing the paste into a mold of a predetermined shape, and allowing the paste to harden into a PCA calcium phosphate article. Brown fails to teach or suggest the preparation of a bioceramic PCA calcium phosphate composition by mixing the powders of a calcium phosphate with any of the promoters listed in present claim 138. Because Brown fails to teach or suggest every element of present claim 138, the requirements for establishing a rejection under 35 U.S.C. § 102 have not been met (see M.P.E.P. § 2131, *supra*). Therefore, Applicants respectfully request that the rejection of claims 138, 140-145, and 148 under 35 U.S.C. § 103(a) over Brown be withdrawn.

### Rejections under 35 U.S.C. § 103(a)

#### *Constantz*

Claims 40, 42, 43, 103, 111-118, 120-123, 125, 127-131, 133-147, and 149-151 are rejected under 35 U.S.C. § 103(a) for obviousness over Constantz. The Examiner states that “[t]he rejection of record is maintained - again, constantz does provide poorly crystalline materials...[and] applicants claim to functional aspects and non-quantified aspects of the invention are seen as obvious over constants [sic] disclosure” (Office Action, p. 3). Applicants

respectfully disagree.

The M.P.E.P. § 2143.03 states that to establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art.

In the previous Office Action, dated January 17, 2003, the Examiner elaborated his rejection stating:

...the density and compression...[of] the Constantz products are of the density and compression (col. 10) as would result from [sic] use of the equipment, presses, disclosed at col. 8, line 38-43)...Column 7 recites a variety of objects and formed product, flowable or formable (lines 38-48), 60-63, col. 7). Although no specific structural geometry is identified, the fact that dry ingredients are combined and mixed (col. 8, lines 3-21) speaks for at least a powder or shaped form, of Apatitic CaP; the instant claim 43 compositions. See also col. 9, line 5-free flowing mixes. (Office Action dated January 17, 2003, pp. 3-4.)

As is discussed above, Constantz fails to teach or suggest any method that would result in the formation of a compressed powder object. The Examiner argues that the equipment disclosed by Constantz would yield a product that has the density and compression elements of the compressed powder object recited in present claims 40, 43, and 103, and claims dependent therefrom. The Examiner relies on several passages from Constantz to support this conclusion. The first passage relied on by the Examiner, col. 10, discloses testing the compressive strength of the Constantz composition, which, as is discussed above, is formed by thoroughly mixing and uniformly dispersing dry ingredients, followed by a hydration step, which results in a hardened carbonated hydroxyapatite. This passage fails to teach or suggest a method in which mixed calcium phosphate powders are compressed to form a compressed powder object, as is recited in present claims 40, 43, and 103. In contrast to the Constantz method, Applicants' method requires first mixing the calcium phosphate powders and then compressing the powders to form a compressed powder object having a predetermined shape (claim 40). The compressed powder

object is subsequently hydrated to promote conversion of the calcium phosphate powder to a hardened PCA calcium phosphate composition (claims 43 and 103). Constantz clearly fails to teach or suggest the formation of a compressed powder object. Therefore, all of the limitations of present claims 40, 43, and 103, and claims dependent therefrom, are not taught or suggested by Constantz and a *prima facie* case of obviousness has not been established (see M.P.E.P. § 2143.03).

The Examiner also relies on Constantz' disclosure at col. 8, line 38-43, which describes the use of ball mills, planetary mills, centrifugal mills, mechanofusion systems, air pulverizers, jet mills, vibratory mills, colloid mills, attrition mills, disc mills, and the like for mixing the reactants that form the Constantz composition. The Examiner argues that the use of the equipment disclosed by Constantz would result in the formation of a compressed powder object according to claims 40, 43, and 103. Applicants again point out that there is no mention, in this passage or elsewhere in Constantz, of presses or other equipment capable of compressing powders. The mixing techniques identified by Constantz are conventional techniques for producing uniformly-dispersed, free-flowing powders, not compressed materials. Thus, although Constantz mixes dry ingredients to produce a free-flowing powder composition, there is no suggestion that the powder is compressed or otherwise shaped. In fact, Constantz discloses that only the hydrated paste may be shaped (see col. 4, lines 47-54, and col. 9, lines 58-64). Given that Constantz fails to teach or suggest every limitation of independent claims 40, 43, and 103, i.e., a compressed powder object having a predetermined shape, Applicants respectfully request that the rejection of claims 40, 43, and 103, and claims 111-118, 120-123, 125, 127-131, 133-137, and 151 dependent therefrom, under 35 U.S.C. § 103(a) for obviousness over Constantz be

withdrawn.

Constantz also fails to teach or suggest every element of present claims 42 and 138. As is discussed above with respect to claim 42, Constantz fails to teach or suggest the combination of a calcium phosphate with any one of the supplemental materials recited in present claim 42.

Constantz also fails to teach or suggest a method for preparing a bioceramic composition by mixing powders of a calcium phosphate with any one of the promoters listed in present claim 138. Therefore, Constantz clearly fails to teach or suggest each and every element of present claims 42 and 138, and claims dependent therefrom. Accordingly, Applicants respectfully request that the rejection of claims 42 and 138-148 under 35 U.S.C. § 103(a) for obviousness over Constantz be withdrawn. Furthermore, this rejection should not be applied to new claims 152 and 153, which depend from claim 42.

*Brown or Constantz in view of Fukase and Tung*

Claims 40, 42, 43, 103, and 111-151 are also rejected under 35 U.S.C. § 103(a) for obviousness over Brown or Constantz in view of Fukase and Tung. The Examiner states that “[a]lthough Fukase and Tung do not compress, they do show the advantages of utilizing the instant materials, however they are characterized, to enhance application of bone pastes and coments [sic] [and] Tung does teach poorly crystalline (amorphous) Ca P” (Office Action, p. 4). Applicants respectfully disagree.

Fukase discloses the preparation of a calcium phosphate composition (CPC) by combining tetracalcium phosphate with anhydrous dicalcium phosphate, which yields a crystalline hydroxyapatite composition (see, e.g., 1852). Fukase describes testing the CPC

composition for its maximum compressive strength as a function of setting time (see, e.g., page 1854).

Tung describes amorphous calcium compounds for use in remineralizing teeth (see, e.g., col. 2, lines 44-48). Specifically, Tung identifies three suitable amorphous calcium compounds: ACP; ACP fluoride (ACPF); and amorphous calcium carbonate phosphate (ACCP), which convert to apatite under physiological conditions, thereby permitting rapid remineralization of dental tissue (see, e.g., col. 2, lines 44-48 and col. 3, lines 29-42). Significantly, Tung discloses only single component calcium phosphate systems (see, e.g., col. 4, lines 43-52).

Fukase and Tung clearly fail to teach or suggest the preparation of a compressed powder object, as is recited in present claims 40, 43, and 103; a fact which is acknowledged by the Examiner. Fukase and Tung also fail to teach or suggest the preparation of a composite material that comprises a PCA calcium phosphate having a Ca/P ratio of less than 1.5 in contact with any one of the supplemental materials recited in present claim 42, and a method of preparing a bioceramic composition by mixing a calcium phosphate with any one of the promoters listed in present claim 138 to obtain a PCA calcium phosphate. Because Fukase and Tung do not cure the deficiencies of Constantz and Brown, the combination of Fukase and Tung with either Constantz or Brown fails to establish a *prima facie* case of obviousness (see M.P.E.P. § 2143.03, *supra*). Therefore, Applicants respectfully request that the rejection of claims 40, 42, 43, 103, and 111-151 over Constantz or Brown in view of Fukase and Tung should be withdrawn.



CONCLUSION

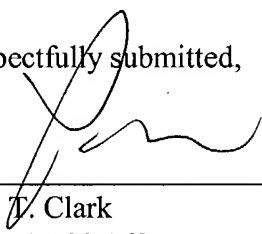
In view of the above remarks, Applicants respectfully submit that the claims are in condition for allowance, and such action is respectfully requested.

Enclosed is a petition to extend the period for replying for three months, to and including May 20, 2004, and a check for the fee required under 37 C.F.R. § 1.17(a).

If there are any other charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

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